OCT - 6 2000

K002592

## 510(k) SUMMARY

### SUBMITTED BY

Prosie Rey-Fessler
Director, Quality Assurance and Regulatory Affairs
INTERPORE CROSS International
181 Technology Drive
Irvine, California 92618

(949) 453-3200

August 18, 2000

This summary of 510(k) substantial equivalence information is being submitted in accordance with the requirements of 21 CFR §807.92.

### CLASSIFICATION, COMMON OR USUAL NAME, DEVICE NAME

Classification Name: Spinal intervertebral body fixation orthosis.
Common/Usual Name: Appliance, Fixation, Spinal Intervertebral Body
Product Classification: Class II
Proprietary Name: INTERPORE CROSS Anterior Cervical Plate System

### PREDICATE DEVICE

The predicate device is the Codman Anterior Cervical Plate System manufactured by Johnson and Johnson Orthopaedic.

### INDICATIONS-FOR-USE

The INTERPORE CROSS Anterior Cervical Plate System is intended for anterior interbody screw fixation of the cervical spine. This system is indicated for use in the temporary stabilization of the anterior spine from $C_2$ to $C_7$ during the development of cervical spinal fusions in patients with: degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies); trauma (including fractures); primary and metastatic malignant tumors; deformity (defined as kyphosis, lordosis, or scoliosis); pseudarthrosis; failed previous fusions; and/or spinal cord stenosis and cervical myelopathy.

### DEVICE DESCRIPTION

The INTERPORE CROSS Anterior Cervical Plate System consists of a variety of shapes and sizes of bone plates and screws constructed of Ti 6Al 4V, ASTM F136. The plates are provided in either the "slotted" or "fixed hole" designs and both designs are available in 1-5 level plates. The screws are supplied color coded to identify their different lengths. Fixation is provided by bone screws inserted into the vertebral body of the cervical spine using an anterior approach.

NOTE: This device system is intended for anterior cervical intervertebral body fusion only.

## COMPARISON TO THE PREDICATE DEVICE

The INTERPORE CROSS Anterior Cervical Plate System is substantially equivalent to the Codman Anterior Cervical Plate System. Both implants are used to treat similar or the same conditions, have essentially the same precautions and contraindications for use, and have equivalent potential for complications for the risk of use. In addition, they both represent a long standing, basic design concept and differ only in minor details. Based on the design features, the materials of construction and indications for use, INTERPORE CROSS International believes that sufficient evidence exists to reasonably conclude that this device is substantially equivalent to an existing legally marketed implant.

## DISCUSSION OF NONCLINICAL TESTS

Data regarding the functional performance of the proposed INTERPORE CROSS Anterior Cervical Plate System have been generated. Testing was performed in accordance with ASTM F 1717-98 and was conducted on both the "slotted" and "fixed hole" plate designs. Test results are included in Section 3 as well as in Appendix 2.



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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 6 2000

Ms. Prosie Rey-Fessler
Director, Quality Assurance and Regulatory Affairs
INTERPORE CROSS International
181 Technology Drive
Irvine, California 92618-2402

Re: K002592
Trade Name: Interpore Cross Anterior Cervical Plate System
Regulatory Class: Class II
Product Code: KWQ
Dated: August 18, 2000
Received: August 21, 2000

Dear Ms. Fessler:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**510(k) Number (if known):** K002592

**Device Name:** **INTERPORE CROSS Anterior Cervical Plate System**

## Indications-For-Use:

The INTERPORE CROSS Anterior Cervical Plate System is intended for anterior interbody screw fixation of the cervical spine. This system is indicated for use in the temporary stabilization of the anterior spine from $C_2$ to $C_7$ during the development of cervical spinal fusions in patients with: degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies); trauma (including fractures); primary and metastatic malignant tumors; deformity (defined as kyphosis, lordosis, or scoliosis); pseudarthrosis; failed previous fusions; and/or spinal cord stenosis and cervical myelopathy.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Milhous

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002592 10/6/00

**Prescription Use** ✓ **OR** **Over-The-Counter Use**
**(PER 21 CFR 801.109)**

(Optional Format 1-2-96)